SEP 17 2010

510(k) SUMMARY

510(K) SUMMARY

510 (K) Number K101906
Device Name: Shape to Fit Compression Socks

Indications for Use: Help prevent edema and leg discomfort, and help prevent deep vein thrombosis in individuals subjected to immobility.

Over-The-Counter Use

Classification Name: Medical Support Stocking (21 CFR 880.5780, Product Code DWL. This submission covers the indication that Shape to Fit Compression Socks(including same products offered for OEM applications) help encourage circulatory wellness and prevent, ankles and feet, and alleviate swelling in legs and help prevent deep varicose veins. These products fall under the device classification of medical support stockings (21 CFR 880.5780), Class II medical device, Product Code DWL. Shape to Fit Compression Socks (including same products offered for OEM applications) that belong to this category, and they are substantially equivalent to (K062873) Medical Support Stocking(Brand Name Supolar Netex Stockings), Therafirm anti-embolism stockings, Knit-Rite Inc (K091141) and Jobst Institute Inc. (K032325).

Shape to Fit Compression Socks and their substantial equivalents, mentioned above, are compression socks knitted by circular knit machines with nylon and spandex. They all include knee-high which are sized based on ankle and calf circumference fit. Shape to Fit Compression Socks provide controlled, uniform graduated compression, as is provided in all of these substantially equivalent products, starting with more compression circumferentially at the ankle at approximately 15 mmHg to 20 mmHg / 20 mmHg to 30 mmHg (based on average ankle size) then gradually decreases up to the proximal end.

The Shape to Fit products being submitted are substantially equivalent to the predicate product in material content, function and indication and as such can be considered as safe and effective as the referenced, predicate products. This statement is to assure that Shape to Fit Compression Socks is safe and effective when worn for their intended purpose and fit properly according to the guidelines. See Section on Performance Testing –for nonclinical testing that demonstrates that the device is safe, effective, and performs in comparison to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Peggy Kuo
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Tsung Hau Technology Company, Limited
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SEP 17 2010

Re: K101906
Trade/Device Name: Shape to Fit Compression Socks
Regulation Number: 21 CFR 880.5780
Regulation Name: Medical Support Stocking
Regulatory Class: II
Product Code: DWL
Dated: August 26, 2010
Received: August 26, 2010

Dear Ms. Kuo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101906

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INDICATION FOR USE

Indications for Use

510(k) Number (if known):K 101906

Device Name: Shape to Fit Compression Socks

Indications for Use:

Help prevent edema and leg discomfort, and help prevent deep vein thrombosis in individuals subjected to immobility

Prescription Use _____ AND/OR Over-The-Counter Use__X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

9/7/10

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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